

Development and Validation of a Predictive Score and Application of Ultrasound for Difficult Caudal Epidural Blockade in Adult Patients—A Prospective Study

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**Development and validation of a predictive score and application of ultrasound
for difficult caudal epidural blockade in adult patients: A prospective study**

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Predictive score and ultrasound for Difficult caudal epidural blockade

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Abstract:

Background: We aimed to develop a predictive difficult caudal epidural blockade (pDCEB) model when ultrasound was not available and verify the role of ultrasound in difficult caudal epidural blockade(CEB).

Methods: This study consisted of three phases. First, we prospectively enrolled 202 patients and assessed risk factors to develop the predictive scoring system. Second, we enrolled 87 patients to validate it. Third, we enrolled 68 patients with a high risk of difficult CEB (pDCEB score ≥ 3) and randomized them into ultrasound and landmark groups to verify the role of ultrasound.

Result: The rate of difficult CEB was 14.98% overall 289 patients. We found a correlation of unclear palpation of the sacral hiatus (OR 9.688) and cornua (OR 4.725), number of the sacral hiatus by palpation ≥ 1 (OR 4.451), and history of difficult CEB (OR 39.282) with higher possibility of difficult CEB. The area under the receiver operating characteristic curve of the pDCEB model involving the aforementioned factors was 0.889 (95% CI, 0.827-0.952) in the development cohort and 0.862 (95% CI, 0.747-0.977) in the validation cohort. For patients with a pDCEB score ≥ 3 , pre-procedure ultrasound scan could reduce the incidence of difficult CEB.

Conclusion: This novel pDCEB score, which takes into account palpation of the sacral hiatus/cornua, number of the sacral hiatus by palpation ≥ 1 , and history of difficult CEB, showed a good predictive ability of difficult CEB. The findings suggested that performing an ultrasound scan is essential for patients with a pDCEB score ≥ 3 .

Trial registration:

No: ChiCTR1800018871,

Site url: <https://www.chictr.org.cn/edit.aspx?pid=31875&htm=4>

Principal investigator : Jialian Zhao,

Date of registration: 2018.10.14

Key words: Caudal anaesthesia; Regional anesthesia ; Predictive model;

Ultrasonography.

1. Introduction

Caudal epidural blockade (CEB) is one of the most common techniques performed on paediatric patients[1, 2]. Moreover, it is used in several adult surgical techniques, such as prostate biopsy[3], anorectal surgery[4], and treatment of lumbar spinal disorders or chronic back pain[5]. Compared with other neuraxial techniques, such as spinal or epidural blocks, caudal blocks are rarely associated with hypotension and bradycardia given its lower sympathetic blockade[1]. This indicates that CEB may have advantages in patients with advanced cardiac disease or other diseases[6, 7]. Performing a CEB is simple and easy to learn; however, a rate as high as 25% of incorrect needle placements, even with experienced anaesthesiologists, has been reported in several patients[8]. Like other neuraxial blockades, CEB difficulties are mainly associated with the quality of palpable surface landmarks[9-11]. Successful performing a CEB mainly depends on the accurate identification of the sacral hiatus, which is usually easily palpable but with considerable anatomical variations. Up to now, there still no predictive assessment protocol for difficult CEB in adult patients.

The ultrasound technique has been applied to improve peripheral nerve blockade and central neuraxial interventions[12-14]. It can be used to provide sonographic images that show anatomical variations of the sacral hiatus, which is currently regarded as a gold standard for correct needle placement in the CEB technique[15, 16]. However, ultrasound guided CEB may not available in resource limited regions/hospitals and needs for much more experience and ultrasound technique of anaesthetists. In many hospitals of developing countries or regions, there was only

one or even no ultrasound device in department of anesthesiology. It is only recommended in cases where anatomical detection of the sacral hiatus is difficult, especially via palpations[17-19]. Therefore, it is necessary to develop a scoring model for difficult CEB using surface anatomical landmarks and clarify the role of ultrasound to the clinical anaesthetist in cases of difficult caudal epidural block (DCEB).

We hypothesized that palpations and other objective factors can predict difficult CEB well. Thus, we aimed to assess the risk factors for DCEB and develop a predictive difficult caudal epidural block (pDCEB) scoring system based on the surface anatomical landmarks and other factors. In addition, we aimed to determine whether a pre-procedure ultrasound scan can facilitate the CEB procedure in these patients.

2. Methods

2.1. Study design and participants

This prospective study was carried out at the First Affiliated Hospital of Zhejiang University (Hangzhou, China) after being approved by the Ethics Committee (2017-10) and registered in the Chinese Clinical Trial Registry (ChiCTR1800018871, site url: <https://www.chictr.org.cn/edit.aspx?pid=31875&htm=4> Principal investigator : Jialian Zhao, Date of registration: 2018.10.14). Moreover, we obtained written informed consent from the patients or their authorized legal representatives. We enrolled patients undergoing anorectal surgery and scheduled to undergo caudal epidural anaesthesia with an American Society of Anaesthesiologists (ASA) physical status of I–II. We excluded patients with sacrococcygeal diseases such as spinal meningocele, teratoma, and infection; with coagulation defects; or refusing caudal epidural anaesthesia. Methods and reporting of the study adhered to the applicable checklist in accordance with the TREND guidelines.

From October 31st 2018 to March 31st 2019, we enrolled a total of 375 patients scheduled for anorectal surgery in three phases. In the development cohort (phase one), we included 215 patients were included, among whom we excluded 13 patients with teratoma (n = 1), coagulation defects (n = 6), infection at the puncture site (n = 2), and those who refused CEB (n = 4). In the validation cohort (phase two), we included 90 patients, among whom we excluded 3 patients were excluded according to the exclusion criteria (2 for coagulation defects, and one for refusing CEB). We finally included 202 and 87 patients in the development and validation cohort, respectively.

In the third phase, we included 70 patients with a pDCEB score ≥ 3 and included 32 patients in the Ultrasound (Us) group and 36 in the Landmark (Lm) group(Figure1).

Five senior anaesthesiologists with more than five years of CEB experience were arranged to perform the palpation and CEB in the development cohort and three others in the validation cohort. These eight senior anaesthesiologists also conduct in the third step. An assistant recorded the patients' information, palpation, and the CEB inducer and also assisted the anaesthesiologist in performing the ultrasound.

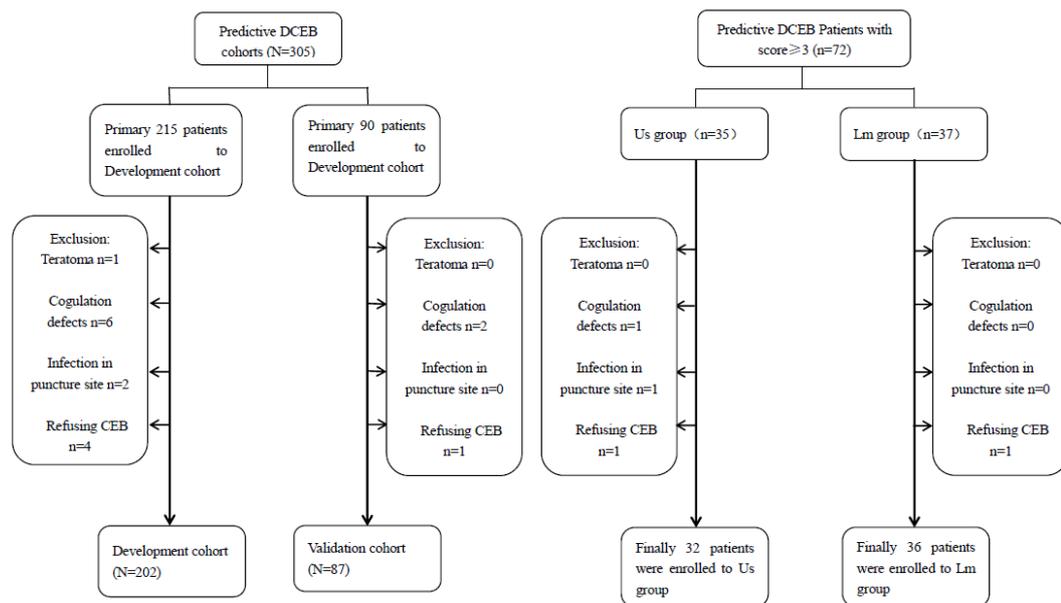


FIGURE 1: From October 31st 2018 to March 31st 2019, we enrolled a total of 377 patients scheduled for anorectal surgery in three phases. In the development cohort (phase one), we included 215 patients were included, among whom we excluded 13 patients with teratoma (n = 1), coagulation defects (n = 6), infection at the puncture site (n = 2), and those who refused CEB (n = 4). In the validation cohort (phase two), we included 90 patients, among whom we excluded 3 patients were excluded according to the exclusion criteria (2 for coagulation defects, and one for refusing CEB). We finally included 202

and 87 patients in the development and validation cohort, respectively. In the third phase, we included 72 patients with a pDCEB score ≥ 3 and finally included 32 patients in the Ultrasound (Us) group and 36 in the Landmark (Lm) group after exclusion.

2.2. Development of pDCEB

2.2.1. Preparation and monitoring

Patients were placed in prone position with the pelvis supported by a pillow and standard monitoring equipment (three-lead electrocardiogram, noninvasive blood pressure, respiratory rate, pulse rate, and pulse oximetry) were implemented. They were administered with 1–2 mg intravenous midazolam for anxiety.

2.2.2. Assessment and palpation

Before the CEB procedure, the anaesthetists palpated the surface landmarks (sacral hiatus and sacral cornua) and recorded the corresponding assessments of the sacral hiatus and cornua. Palpation of the sacral hiatus was classified as either clear/easy to palpate or unclear /difficult to palpate while the assessment of the sacral cornua was classified as either clear or unclear. Sometimes more than one pits may be palpated in the sacral caudal area. If the number of the “sacral hiatus” by palpation was > 1 (more than one pits was palpated in sacral area), the number was recorded and the anaesthetist, based on their experience, would determine an optimal puncture site.

2.2.3. CEB Procedure

After being sterilized and draped, a 22 G-needle was inserted to the predetermined puncture site. Once there was loss of resistance and no blood or fluid was aspirated, we placed the sterile ultrasound probe of 13-6 MHz linear-array (Sonosite Inc., Bothell, WA, USA or Mindray Inc., Shenzhen, China) transversely to the caudal canal a few centimetres above the needle insertion point. Colour flow Doppler imaging was utilized during the actual injection into the caudal epidural space. If the presence of real-time turbulence or colour flow within the caudal space during the injection accompanied with the dilation of the caudal canal (Figure 2A), we considered the puncture successful [2, 16, 20] and administered lidocaine and ropivacaine. If the ultrasound indicated the puncture was not successful, the anaesthesiologist attempted another puncture until it met the criteria to be successful or failed. After administering a test dose, 10 mg lidocaine (1%) and 7.5 mg ropivacaine (0.375%) were injected into the caudal space.

2.2.4. Data collection

The duration of the puncture (from the first needle insertion into the skin to the ultrasound confirming the puncture as successful), the number of needle passes (once the needle move, there was one count of needle passes), the number of attempts (once the needle was withdrawaled and a new palpation was conducted, there was one count of attempts) during the whole procedure were recorded. DCEB was defined as one

where the duration of the puncture was longer than 5 minutes or with more than 10 needle passes or more than 3 attempts . We recorded other objective variables, such as age, Body Mass Index (BMI), a history of DCEB, a history of sacrococcygeal diseases (fracture, Ankylosing spondylitis, etc.) before the CEB procedure.

2.3. Validation of pDCEB

For the validation cohort, all the assessments of the surface landmarks and the CEB procedure were similar to those of the development cohort except for the fact three other senior anaesthesiologists were arranged to perform the palpation and CEB.

2.4. Ultrasound for predicting patients at risk of DCEB

We selected a predictive difficult caudal epidural block (pDCEB) score of 3 with largest Youden-index as the cut off value with a score above this being predictive of DCEB. In the Us group (n = 32), the patients underwent a pre-procedure ultrasound scan to assess the anatomy of the sacral hiatus, sacral cornua, and caudal space, which together with palpation, was used by the anaesthesiologist to determine the puncture site (Figure 2B, C). In the Lm group (n = 36), the anaesthesiologist palpated the surface landmarks of the sacral hiatus and sacral cornua to determine the puncture site. The rest of the puncture procedure was the same as the above mentioned. The time taken to establish the puncture site (from the start of the pre-procedure ultrasound

scan/palpation to the start of needle insertion, including sterilizing and draping), duration of the puncture, the total number of needle passes/attempts, the rate of success on the first needle pass, the rate of DCEB, and the patients' satisfaction were recorded.

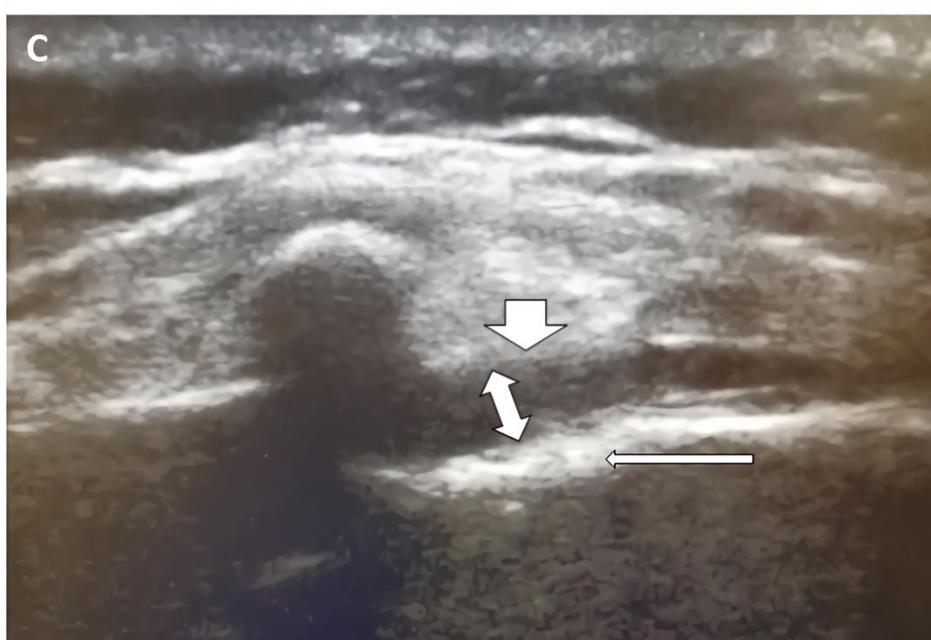
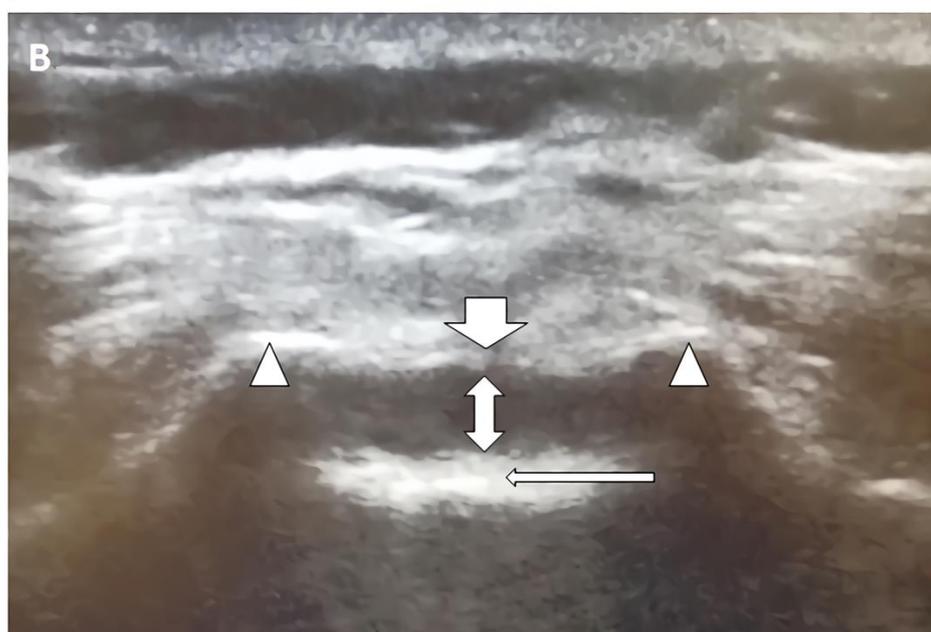
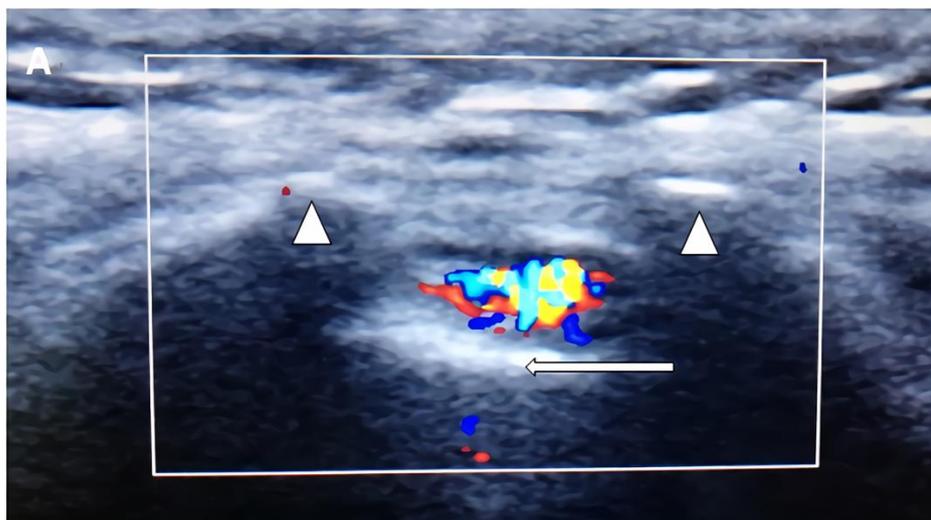


FIGURE 2: Colour flow Doppler imaging of a “successful puncture” (A). Ultrasound images of the transverse (B) and longitudinal (C) plane of the sacral hiatus. Real-time turbulence or colour flow and expansion of the caudal space during injection can be seen. The area of turbulence or colour flow is the caudal space. The “white triangle” represents the sacral cornua, the “downward arrow” represents the sacrococcygeal ligament, the “leftward arrow” represents the base of the sacrum posterior surface, and the “double-ended arrow” represents the caudal space.

2.5. Statistical Analysis

Quantitative variables were presented as mean \pm SD or median (interquartile range, IQR) and analysed using Student’s t-test or Mann–Whitney test while categorical variables were presented as n (%) and analysed using chi-square test. Significant variables after univariate analysis were subjected to binary logistic regression (Forward, LR) to fit the predictive model with an entry level of 0.05 and an exclusion level of 0.10. The goodness of fit of a model was judged using Hosmer–Lemeshow test and receiver operating characteristic (ROC) curve. An area under the ROC curve (AUROC) > 0.75 was considered to have good predictive ability. Youden-index was used to determine the cut off value. Patients with a pDCEB score equal or more than 3 were predicted to be at risk of DCEB. All the statistical tests were two-sided and performed by SPSS 20.0 software. Differences with a P value < 0.05 were considered significant.

3. Results

3.1. Development of the pDCEB

3.1.1. Basic characteristic and Risk Factors

In the development cohort, the rate of DCEB was 14.85%. There were no significant differences in the patients' basic characteristics regarding gender, age, and BMI. Unclear palpation was much more common in the DCEB cases, including unclear palpation of the sacral hiatus (66.67% vs. 11.63% in the controls, $p < 0.001$) and cornua (73.33% vs. 23.84% in the controls, $p < 0.001$). Patients with more than one "sacral hiatus" by palpation and history of DCEB were associated with DCEB ($p < 0.001$). Patients with DCEB were less satisfied with the procedure. Detailed information is listed in Table 1.

TABLE 1: Basic characteristics of the development and validation cohort

Characteristics N = 289	Development Cohort N = 202			Validation Cohort N = 87		
	DCEB (N = 30)	No DCEB (N = 172)	P value	DCEB (N = 13)	No DCEB (N = 74)	P value
Male	22 (73.33%)	127 (73.84 %)	0.954	11 (84.62%)	49 (66.22%)	0.186
Age	45.10 ± 14.08	41.82 ± 14.73	0.249	41.69 ± 11.93	4.22 ± 13.85	0.898
BMI	23.67 ± 3.72	23.43 ± 3.41	0.747	24.85 ± 3.76	22.43 ± 3.15	0.045*
A history of difficult CEB	3 (10.00%)	1 (0.58%)	0.011	2 (15.38%)	0 (0.00%)	0.001*
Distance between	6.5 (6.0-7.125)	6.5 (6.0-7.0)	0.855	7.5 (7-8)	7 (6.875-7.5)	0.253

puncture site and						
coccygeal apex (cm)						
Number of “Sacral			0.006			0.001*
hiatus” by Palpation						
1	17 (56.67%)	141 (81.98%)		6 (46.15%)	57 (77.03%)	
2	10 (33.33%)	26 (15.12%)		3 (23.08%)	15 (20.27%)	
≥3	3 (10.00%)	5 (2.90%)		4 (30.77%)	2 (2.70%)	
Unclear palpation of	20 (66.67%)	20 (11.63%)	< 0.001*	6 (46.12%)	5 (6.76%)	< 0.001*
sacral hiatus						
Unclear palpation of	22 (73.33%)	41 (23.84%)	< 0.001*	9 (69.23%)	16 (21.62%)	< 0.001*
sacral cornua						
Patient and surgeon			< 0.001*			< 0.001*
satisfaction						
very satisfied	15 (50.00%)	153 (88.95%)		5 (38.46%)	71 (95.95%)	
satisfied	6 (20.00%)	17 (9.88%)		5 (38.46%)	2 (2.70%)	
dissatisfied	9 (30.00%)	2 (1.16%)		3 (23.08%)	1 (1.35%)	
Success On 1st	0 (0.00%)	91 (45.05%)		0 (0.00%)	40 (47.06%)	-
needle pass						

BMI: Body Mass Index; CEB: Caudal Epidural Blockade/Block.

The values are presented as mean ± standard deviation (SD), median (interquartile range, IQR), or n

(%). Normally distributed continuous variables are presented as “Mean ± SD” while abnormally

distributed ones are presented as “Median, IQR”. Categorical variables are presented as “n (%)”. Each

*P value < 0.05 was considered to be significant. The P value was obtained by Student's t-test or Mann-Whitney test for continuous variables and chi-square test for categorical variables.

3.1.2. Establishment of pDCEB model

Findings of multivariate logistic regression analysis of the predictors of DCEB are listed in Table 2. Unclear palpation of the sacral hiatus (OR, 9.688; 95% CI, 3.323-28.201) and sacral cornua (OR, 4.725; 95% CI, 1.577-14.151), number of the “sacral hiatus” by palpation ≥ 1 (OR, 4.451; 95% CI, 1.520-13.031), and a history of DCEB (OR, 39.282; 95% CI, 2.751-560.827) were correlated with a higher possibility of DCEB.

To meet the objective of developing a simplified model that could calculate the risk of DCEB by simply counting the number of risk factors, we finally rounded off the coefficients. Therefore, we developed the pDCEB and obtained the final score as the summation of the difficulty predictors of each patient (Table 2). The simplified DCEB score is:

The simplified DCEB score = 1.5*. More than one “sacral hiatus” by palpation + 4*. A history of difficult CEB + 2*. Inability or uncertainty to palpate sacral hiatus + 1.5*. Inability or uncertainty to palpate the sacral cornua.

ROC was used to evaluate the predictive efficiency of the difficulty score (Figure 3). The AUROC in the development cohort was 0.889 (95% CI, 0.827-0.952; $p < 0.001$). Based on the sensitivity and specificity of the simplified pDCEB score, the

cut-off value was 2.5 with largest Youden-index of 0.628 (sensitivity = 0.733 and specificity = 0.895). Therefore, we selected a score of 3 as the cut off value with a score of this and above being indicative of a risk of DCEB.

TABLE 2: Risk factors associated with difficult caudal epidural block and the simplified model of pDCEB score

Covariants	β Coefficient	OR	OR 95% CI	P value	Point
More than one sacral hiatus	1.493	4.451	1.520-13.031	0.006	1.5
A history of difficult CEB	3.671	39.282	2.751-560.827	0.007	4
Unclear palpation of sacral hiatus	2.271	9.688	3.323-28.201	< 0.001	2
Unclear palpation of sacral cornua	1.553	4.725	1.577-14.151	0.006	1.5
Constant	-3.911	0.02	-	< 0.001	-

Hosmer -Lemeshow test P = 0.732

The risk was calculated using odds ratio [OR] (confidence interval [CI]). Each P value < 0.05 was considered significant. All the variants entered into the regression analysis were categorical: more than one sacral hiatus by palpation indicated 1 while only one sacral hiatus by palpation indicated 0; a history of difficult CEB indicated 1; inability to palpate or uncertain feeling of the sacral hiatus indicated 1 while clear palpation of the sacral hiatus indicated 0; inability to palpate or uncertain feeling of the sacral cornua indicated 1 while clear palpation of the sacral cornua indicated 0. We used binary logistics regression (Forward, LR) to fit the model with an entry level of 0.05 and an exclusion level of 0.10. The simplified DCEB score = 1.5*. More than one “sacral hiatus” by palpation + 4*. A

history of difficult CEB + 2*. Inability or uncertainty to palpate sacral hiatus + 1.5*. Inability or uncertainty to palpate the sacral cornua.

3.2. Validation of the pDCEB

In the validation cohort, the rate of DCEB was 14.94%. There were no significant differences in the patients' basic characteristics while unclear palpation of the sacral hiatus and cornua, number of the "sacral hiatus" by palpations > 1, and history of DCEB were associated with DCEB (Table 1). The AUROC was 0.862 in the validation cohort (95% CI, 0.747-0.977; $p < 0.001$) and showed a good predictive ability (figure3).

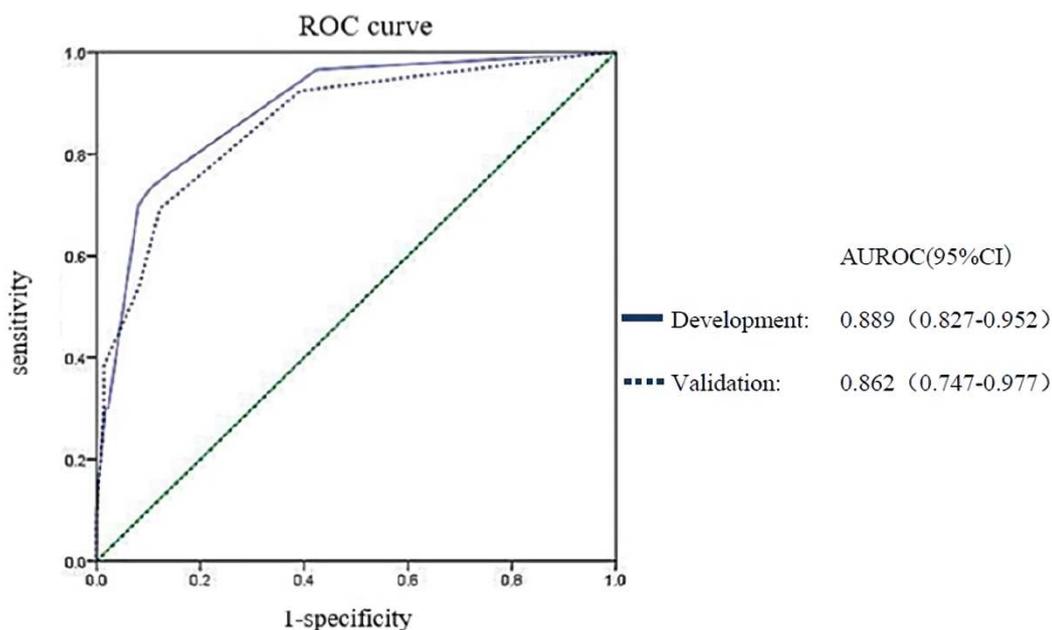


FIGURE 3: ROC curves based on the DCEB scoring model and its respective AUROC (95% CIs).

The blue solid curve is the ROC curve from the development cohort ($n = 202$) while the dotted curve represents the validation cohort ($n = 87$). The ROC curve was used to evaluate the efficiency of

prediction and an area under the ROC curve (AUROC) > 0.75 considered to indicate a good predictive ability.

3.3. Ultrasound for predictive DCEB patients

In the final phase, we enrolled 68 patients with a pDCEB score ≥ 3 with no significant difference in the DCEB score among them (Us 3.5 (3.5-5.0) vs. Lm 3.5(3.5-5.0), $p = 0.736$). The DCEB incidence in the Us group was 9.38%, which was significantly reduced compared with the Lm group (55.56%, $p < 0.001$). In the Us group, the number of needle passes and attempts was significantly reduced (2(1-4) vs. 9(3-15), $p < 0.001$; 1(1-2)vs. 3(1.25-5), $p < 0.001$), the success rate on first needle pass was significantly increased (46.88% vs. 8.33%, $p < 0.001$), and the time to perform CEB was significant reduced (1(1-2.75) vs. 6(2-7.75), $p < 0.001$). Moreover, the Us group needed more time to establish the puncture site; but there was a significant between-group difference in the total procedure (both $p < 0.001$). Patients in the Us group were more satisfied with the anaesthesia. There was no significant between-group difference in the use of a rescue analgesia drug (Table 3).

TABLE 3: Performance of CEB between the ultrasound and landmark group in predictive DCEB patients (DCEB score ≥ 3)

	Ultrasound group (N = 32)	Landmark group (N = 36)	P value
DCEB score	3.5 (3.5-5.0)	3.5(3.5-5.0)	0.736

Difficult CEB	3 (9.38%)	20 (55.56%)	< 0.001*
Success On 1st needle pass	15 (46.88%)	3 (8.33%)	< 0.001*
Time take to establish puncture site	7(6-8)	3(2.25-4.0)	<0.001*
time take to perform CEB	1(1-2.75)	6(2-7.75)	<0.001*
Total procedure time	9 (7-10.75)	9 (5-11)	0.308
Total number of needle passes	2(1-4)	9(3-15)	< 0.001*
Total number of attempts	1 (1-2)	3 (1.25-5.0)	< 0.001*
Rescue Analgesia drug	5 (15.63%)	10 (27.78%)	0.228
Patient's satisfaction			0.001*
Satisfied	28 (87.5%)	17(47.22%)	
Qualified	2 (6.25%)	15(41.67%)	
Dissatisfied	2 (6.25%)	4(11.11%)	

The values are presented as mean \pm standard deviation (SD), median (interquartile range, IQR), or n (%). Normally distributed continuous variables are presented as "Mean \pm SD" while abnormal

distributed ones are presented as “Median, IQR”. Categorical variables are presented as “n (%)”. Each

*P value < 0.05 was considered significant. The P value was obtained by Student’s t-test or Mann–

Whitney test for continuous variables and chi-square test for categorical variables.

4. Discussion

This prospective study demonstrated that unclear palpation of the sacral hiatus and sacral cornua, number of the “sacral hiatus” by palpation ≥ 1 , and history of DCEB were the four predictors of DCEB. We developed the pDCEB score and found that the ROC in the two cohorts both showed good predictive ability. All the patients were stratified into a score range of 0-9 with a score of 3 as the cut off value. For patients with a pDCEB score ≥ 3 , ultrasound-assisted CEB reduced the number of needle passes and the duration of the puncture duration and improved the rate of successful punctures on first needle pass and the patients’ satisfaction.

Palpation of the sacral hiatus was the main factor for determining the difficulty during the caudal epidural injection. Unlike other neuraxial techniques, such as spinal and epidural anaesthesia, age and obesity were not correlated with DCEB, which may be due to the superficial anatomical structure of sacral hiatus and the operation of this procedure[4, 21]. Studies have shown that the distance between the skin and the posterior sacral bony surface is 17.5 ± 4.7 mm and that the distance between the bilateral cornua was 18.1 ± 3.2 mm with ultrasonographic evaluation[22]. There can be considerable variations in the heights and shapes of the sacral hiatus depending on the developmental fusion processes of the sacral vertebrae and ligaments during childhood[2, 20, 23]. In most people, the sacral hiatus is formed by incomplete fusion of the S5 vertebrae in the posterior midline. However, some patients also show incomplete fusion of the lower portion of the S4, S3, or S2 posterior midline[2]. In a few cases, the hiatus has been reported to be absent in the fusion processes or the

sacrococcygeal membrane and cannot be penetrated because of advanced ossification, which has resulted in the failure of CEB[24]. We also found that the sacral cornua, formed by the remnants of the S5 inferior articular processes, are significantly associated with caudal epidural anaesthesia in this study. However, there have been reports of the sacral cornua being impalpable or unilateral in up to 46% to 79% of cases[8, 21], and thus causing the clinical anaesthesiologist difficulty. We found that more than one “sacral hiatus” by palpation was a predictor of DCEB, which might be due to the fake hiatus between the median sacral crest or irregular variations

A successful CEB depends on the accurate placement of the needle into the caudal epidural space; however, There was a certain incorrect needle placement rate even with experienced anaesthesiologists[2, 23]. With advances in medical imaging, fluoroscopy, computed tomography (CT), magnetic resonance imaging (MRI), and ultrasound can all be used to reveal the anatomy of the sacral hiatus and assist the anaesthesiologist while performing the CEB[25-27]. Pre-procedural ultrasound scanning was reported to facilitate spinal anaesthesia by allowing appropriate selection of the intervertebral space, needle alignment, measuring the depth from the skin to dura, reducing the number of attempts, and decreasing the number of bony contacts and associated complications in adult patients with difficult surface anatomic landmarks[28, 29]. Compared with the conventional blind method, ultrasonography can allow one to visualize the anatomic structure of the sacral hiatus and the spread of the local anaesthetic[2, 15, 16, 30]. Ultrasonography has been reported to be superior to the ‘swoosh’ test as an objective confirmatory technique during caudal block

placement and allows 100% accuracy in correct needle placement[15, 31, 32]. Based on this, we chose ultrasound to allow and determine successful punctures. To avoid the influencing factor of the practicing anaesthesiologist, we placed the ultrasound probe a few centimetres cephalad to the point of needle insertion and checked for whether there was accompanying real-time turbulence or colour flow within the caudal space during injection with dilation of the caudal canal.

Ultrasound is a valuable tool for identifying anatomical landmarks of the sacral hiatus in CEB[22, 33]. Compared with the conventional landmark technique, pre-procedural ultrasound or ultrasound-guided CEB conferred superior advantages since it allows real-time visualization of the anatomical structures and spread of the local anaesthetic[16, 19, 31]. We found that ultrasound reduced the DCEB rate and the total number of needle passes/attempts and increased the success rate on the first needle pass. This might indicate that the traditional landmark-based method should be abandoned. But in resource limited regions/hospitals, an ultrasound may not available for every anaesthetists and it also ask for much more experience and ultrasound technique. Many hospitals in developing countries/regions, there is only one or even no ultrasound in anesthesiology department. Also ultrasound was not suggested in every patient since its high success rate. In pediatric patients, studies have suggested that ultrasound is only essential if the sacral cornua and sacral hiatus were clinically identifiable[19, 34]. In our study, the DCEB rate in the 287 patients was 14.88% while those with a low DCEB score (DCEB score < 3) had a DCEB rate as low as 5.19%. This indicates that ultrasound assistance is not needed for patients with low DCEB

score (DCEB score < 3). Moreover, given the superficial anatomical structure of the sacral hiatus, there was no significant difference between pre-procedure ultrasound and ultrasound-guided CEB.

There are several limitations to this study. One is that the development and validation of this predictive scoring system were both conducted in a single centre. Thus, multicentre studies should be conducted to improve and validate this predictive scoring system for DCEB. The other is that all palpation and assessments of the sacral hiatus area were purely subjective. Even though experienced senior clinical anaesthetists performed the CEB procedure, this could still have resulted in bias.

5. Conclusions

Palpation of the sacral hiatus structures including the sacral hiatus and sacral cornua, number of the “sacral hiatus” by palpation ≥ 1 , and history of DCEB were risk factors associated with DCEB in adult patients. The preoperative score consisting of these four factors showed good predictive ability. Our findings indicated that ultrasound are suggested only in higher risk of DCEB (pDCEB score ≥ 3) cases in order to save resources and cost especially in resources limited regions/hospitals.

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Authors' Contributors:

Jialian Zhao and Guohao Xie contributed equally to this article, both performed the experiments and drafted the article.

Lihua Chu: This author performed statistical analysis.

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Availability of data and materials:

Data from the reported cases will be made available on reasonable request from the corresponding author.

Declarations**Ethics approval and consent to participate:**

This study was approved by the First Affiliated Hospital of Zhejiang University (Hangzhou, China) Ethics Committee (number: 2017-10) and written informed consent was obtained from all subjects participating in the trial.

Trial registration:

This study was registered prospectively in the Chinese Clinical Trial Registry (no. ChiCTR1800018871, site url: <https://www.chictr.org.cn/edit.aspx?pid=31875&htm=4> Principal investigator : Jialian Zhao, Date of registration: 2018.10.14). All methods were performed in accordance with the relevant guidelines and regulations.

Consent for publication:

Informed consent for publication of clinical research was obtained from all patients.

Competing interests:

The authors declare no conflicts of interest.

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